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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/070,026	02/25/2002	David James Hallett	T1502	5905

7590 07/18/2003

Merck & Company Inc
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Rahway, NJ 07065

EXAMINER

SHIAO, REI TSANG

ART UNIT

PAPER NUMBER

1626

DATE MAILED: 07/18/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/070,026	HALLETT ET AL.	
	Examiner	Art Unit	
	Robert Shiao	1626	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on application received on 02/25, 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7, 9 and 10 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 9 is/are rejected.
- 7) ☒ Claim(s) 1-7 and 10 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) <u>7103</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. This application claims benefit of the foreign application:
United Kingdom 9921150.0 with a filing date 09/07/1999.
2. Claims 1-7, and 9-10 are pending in the application.

Election/Restrictions

3. Applicant's election with traverse of electing the compound of Example 8 (page 34, line 31) in Paper No. 6103, dated June 19, 2003, is acknowledged. The traversal is on the grounds that instant invention comprises a common structure core, therefore, it will not be a serious burden on the Examiner if restriction is not required. This is not found persuasive and reasons are given, *infra*.

Restriction is required under 35 U.S.C. 121 and 372.

Claims 1-7, and 9-10 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.1 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 state that unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex. B, Part 1(b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part I(e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (I) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for a use of the said product, or
- (II) in addition to an independent claim for a given process, an independent claim for an apparatus or means specifically designed for carrying out the said process, or
- (III) in addition to an independent claim for a given product, an independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specifically designed for carrying out the said process..."

This application contains the following groups I-III which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 C.F.R. 1.499, applicant is required, in response to this action, to elect a single invention to which the claims must be restricted.

Claims 1-7, and 9-10 are generic to a plurality of disclosed patentably distinct species comprising for example, the compounds designated as (1) a compound of

formula I comprise a variable Z, wherein Z is pyridine, (2) a compound of formula I comprise a variable Z, wherein Z is thiophene, (3) a compound of formula I comprise a variable Z, wherein Z is morpholine.

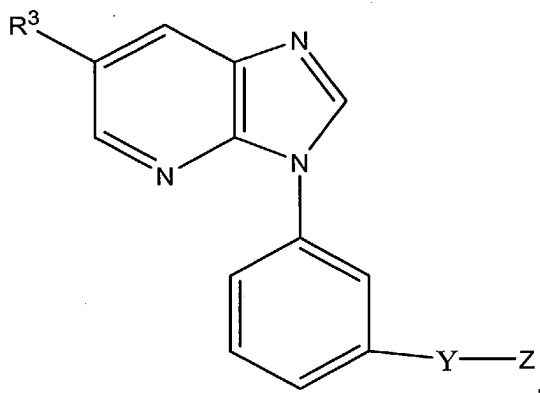
The inventions do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding technical features that defines a contribution over the prior art, see CAS:115:135998. The claimed compounds of formula I comprise a variable Z, and Z is various heteroaryl. Each of the inventions in this applications represent a discrete compound which one skilled in the art which beside sharing no structural element, cannot be said to belong to a recognized class of chemical compounds. Accordingly, the unity of invention is considered to be lacking and restriction of the invention in accordance with the rules of unity of invention is considered to be proper. Groups I-III are independent and distinct because there is no patentable co-action between the groups and a reference anticipating one member will not render another obvious. Each group is directed to art recognized divergent subject matter which require different searching strategies for each group. Moreover, the examiner must perform a commercial database search on the subject matter of each group in addition to a paper search, which is quite burdensome to the examiner.

The requirement is still deemed proper and is therefore made FINAL.

Status of the Claims

4. Claims 1-7, and 9-10 are pending in the application. The scope of the invention of the elected subject matter is as follows:

A compound of formula I of claim 1,



wherein

Y is as defined in claim 1;

Z is an optionally substituted aryl, heteroaryl or

heteroaryl(C₁₋₆)alkyl group, wherein heteroaryl is selected from the group consisting of pyridine, pyrrolidine, imidazole, and thiophene;

or a group of formula -NR¹R², wherein R¹ and R² independently is

hydrogen, hydrocarbon, or a heterocyclic group, wherein heterocyclic group is selected from the group consisting of pyridine, pyrrolidine, imidazole, and thiophene, or R¹ and R², together with the intervening nitrogen

atom, represent an optionally substituted heterocyclic ring selected from

the group consisting of pyridine, pyrrolidine, imidazole, and thiophene; and

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R³ represents aryl or heteroaryl group, wherein heteroaryl is furanyl, and either of each groups may be optionally substituted.

As a result of the election and corresponding generic concept identified, claims 1-7, and 9-10 embraced by above generic concept, are prosecuted in the case, claims 1-7, and 9-10, not embraced by above generic concept, are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a non-elected invention. The withdrawn subject matter of claims 1-7, and 9-10, in part, is properly restricted as it differs materially in structure and in element from the elected subject matter supra so as to be patentably distinct there from, i.e., the fields of search are not co-extensive.

5. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 9 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

For rejections under 35 U.S.C. 112, first paragraph, the following factors must be considered (In re Wands, 8 USPQ2d 1400, 1988):

- 1) Nature of invention.
- 2) State of prior art.

- 3) Level of ordinary skill in the art.
- 4) Level of predictability in the art.
- 5) Amount of direction and guidance provided by the inventor.
- 6) Existence of working examples.
- 7) Breadth of claims.
- 8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

See below:

1) Nature of the invention.

The claim is drawn to a process of making a compound of formula I or “a **further** compound of formula I by standard methods”, see page 41, step (E).

2) State of the prior art.

The references do not indicate which processes for preparing “further compounds of formula I” may be useful in the claimed invention. Applicants cites references on page 4 that pertain to 1-phenylbenzimidazole derivatives with various substituents of the phenyl ring; benzimidazole nucleus can be replaced by any other moiety, with in particular no mention being made of replacement by the imidazo[4,5,b]pyridine functionality.

3) Level of ordinary skill in the art.

The level of ordinary skill in the art is high. The prepared compound of formula I or “a **further** compound of formula I” encompasses a vast number of compounds. Applicant’s specification does not enable the public to prepare such a numerous amount of compounds of formula I by the instant examples disclosed in the specification.

4) Level of predictability in the art.

The art pertaining to related processes of making a compound of formula I or “a **further** compound of formula I” remains highly unpredictable, see claim 9, page 41, line 6. Different types of the genus of formula I require various experimental procedures and without guidance that is applicable to all possible “**further** compounds of formula I”, there would be little predictability in the scope of claimed compounds.

5) Amount of direction and guidance provided by the inventor.

The prepared compounds of the formula I or “a **further** compound of formula I” encompasses a vast number of compounds. Applicant’s limited guidance does not enable the public to prepare such a numerous amount of “**further** compounds of formula I” in the specification. There is no enablement for “a **further** compound of formula I” representing general substituents including cyclic, heterocyclic, aromatic, aliphatic, etc., many of which are neither enabled nor supported in the specification.

6) Existence of working examples.

The process of making the compound of formula I or “a **further** compound of formula I” encompasses a vast number of compounds. Applicant’s limited working examples do not enable the public to prepare such a numerous amount of “**further** compounds of formula I” in the specification. Applicants claim a compound of formula I or “a **further** compound of formula I”, however, the specification provides only 9 examples of the instant compounds.

7) Breadth of claims.

The claims are extremely broad due to the vast number of possible "**further** compounds for formula I".

8) Quantity of experimentation needed to make or use the invention based on the content of the disclosure.

The specification did not enable any person skilled in the art to which it pertains to make or use the invention commensurate in scope with this claim. In particular, the specification failed to enable the skilled artisan to practice the invention without undue experimentation. The skilled artisan would have a numerous amount of modifications to perform in order to obtain compounds or "a **further** compound of formula I" as claimed.

Based on the unpredictable nature of the invention and state of the prior art and the extreme breadth of the claims, one skilled in the art could not perform the claimed process without undue experimentation, see *In re Armbruster* 185 USPQ 152 CCPA 1975. A suggestion to obviate the rejection would be to incorporate the scope of "a **further** compound of formula I" into the claims.

Objection

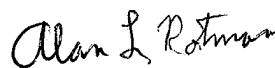
6. Claims 1-7, and 9-10 are objected to as containing a non-elected invention. Claims 2, and 5-6 recite the limitation "salts" and "prodrugs" (page 37, line 21, page 38, line 22, and page 39, line 5), which is objected. Since claims 2, and 5-6 are drawn to a compound and/or its salt or prodrug, therefore, a pharmaceutical acceptable salt and a prodrug are commensurate with the scope of instant claims. Incorporation of "a pharmaceutical acceptable salt or a prodrug thereof" would obviate the objection.

Telephone Inquiry

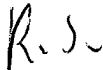
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert Shiao whose telephone number is (703) 308-4002. The examiner can normally be reached on 8:30 AM - 5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph K. McKane can be reached on (703) 308-4537. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 305-3014 for regular communications and (703) 305-3014 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.



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July 15, 2003